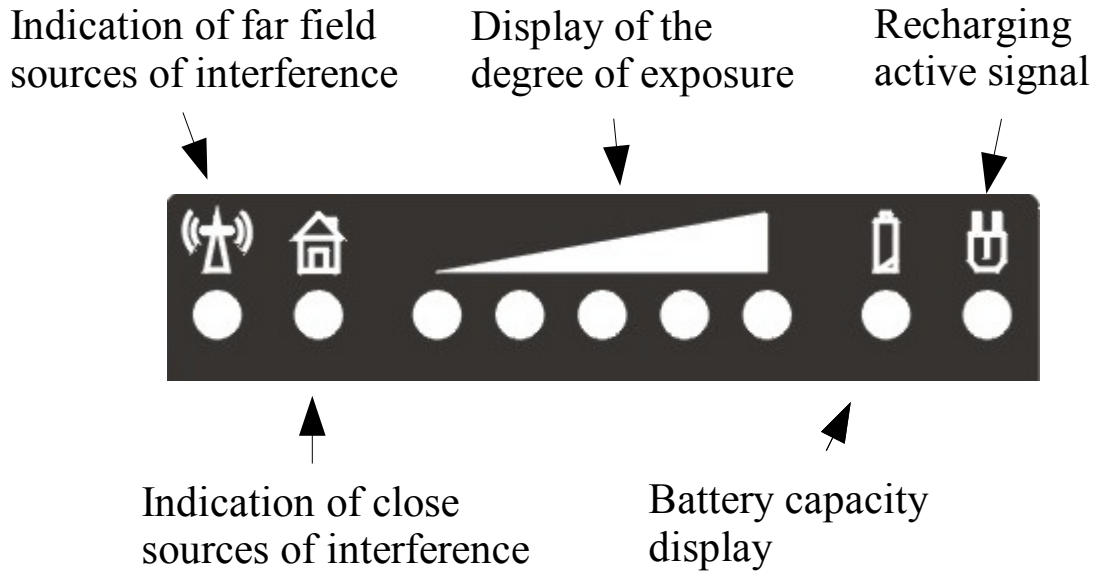
CardioMan

The new warning device
for pacemaker and ICD patients

User manual

Front view

Face side view


Indication of far field sources of interference
Display of the degree of exposure
Recharging active signal
Indication of close sources of interference
Battery capacity display

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Introduction

Congratulations for buying Cardioman®, the device for pacemaker and ICD patients that warns against electric, magnetic, and electromagnetic fields.

Cardioman® is equipped with modern components for optimal detection of different fields. It warns you by visual and acoustic signals against fields that can lead to malfunctions of your pacemaker or ICD.

The sensitivity of the detectors is adjusted in that way, that the warning occurs before critical field strengths are reached. Thus, you can recognize in time which areas or objects you should avoid.

This manual explains the operation and the interface of Cardioman®. Moreover, we give you some tips for maintenance of the warning device as well as some safety information.

Cardioman® enhances your safety in everyday situations. Having the device at your side you can act as relaxed and mobile as you want to.

Operation

On-off-switch

To activate the warning function you have to switch on Cardioman®. If you do not have it in use, you can switch off Cardioman® in order to conserve power.

0
1

The **on-off-switch** is placed on the right side. The device is switched on in position 1. In that case you can see the numbers shining in the display.

Recharging the battery

Cardioman® is equipped with a modern Li-Ion battery. The symbol shines, if the battery charge is too low. Once it starts shining you can use Cardioman® for a period of about 3-5 hours. By the end of this period you must recharge the battery. It is no problem if the battery is occasionally fully discharged.

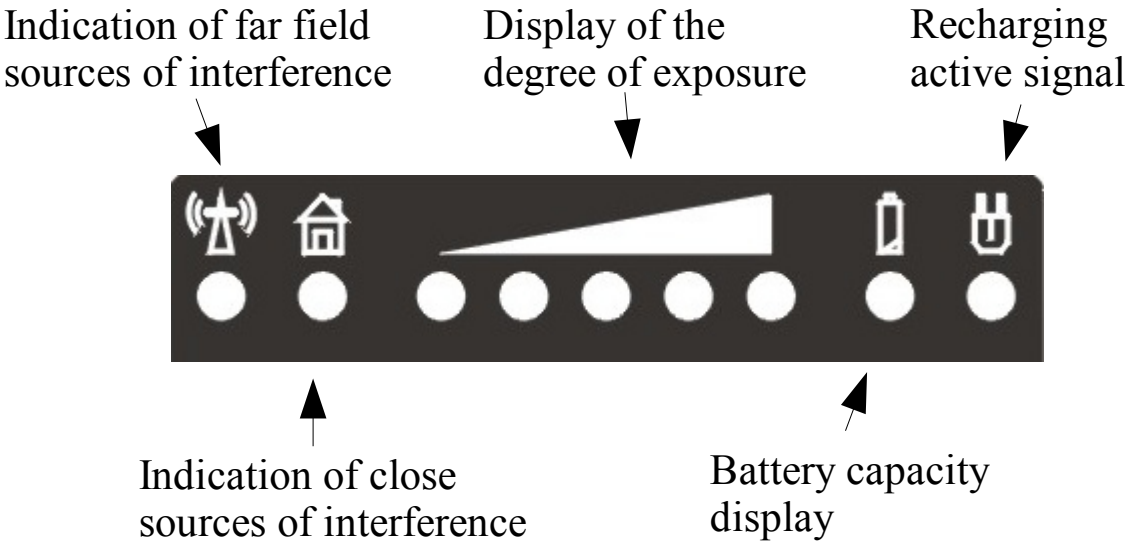
For recharging the battery you have to stick in the cable of the wall power supply included in delivery into the plug socket on the right side of Cardioman®. During the recharging process the signal is shining. When the LED expires the battery is charged to a capacity of 75%. The complete recharging of a fully discharged battery takes about 3 hours.

If the battery is completely charged you can use Cardioman® for a period of about 1.5 days. You should not recharge a battery if it is almost completely charged.

Remarks:
- Please do not use other wall power supplies than that one included in delivery.
- You can recharge the battery within a temperature range between 10°C and 35°C.
- The wall power supply can get warm during a longer recharging process. That is normal and safe.

The displays at a glance

The following figure shows the symbols at the face side of Cardioman®. After that we explain the single elements.


Indication of far field sources of interference
Display of the degree of exposure
Recharging active signal
Indication of close sources of interference
Battery capacity display

Meaning of the displays on the face side

LED line: Display of the degree of exposure

These LEDs shine if you get close to a dangerous field strength. The number of shining LEDs increases if the field strength gets closer to the warning curve. Once the third LED is shining you are beyond the limits. In that case the acoustic beep calls for further attention. The meaning of the warning curve itself is explained together with Cardioman's response curve on page 17.

The abbreviation “LED“ stands for light emitting diode.

Battery symbol: Battery charge

Whenever this signal is shining you should recharge the battery within the next 3 to 5 hours. Please do only use the wall power supply included in delivery (see section “Recharging the battery”).

Plug symbol: Recharging active signal

This LED shines green during the recharging process. It expires as soon as the battery is charged to a capacity of 75 %. A complete recharging process takes about 3 hours (independent of the shining of the LED).

Antenna and house symbol: Indication of far or close sources of interferences

The antenna and the house symbols indicate if a measured source is rather far (shining) or close (shining). This feature is explained in more detail in section “Dependence on the distance” starting on page 11.

LCD Display: Field strength

The currently measured field strength is displayed on the LCD display on the front side. The numbers do not describe the physical value of the field strength, but a relative value coding the distance to the limits of the warning curve. The reason for this is that the critical field strengths have different values for different electromagnetic frequencies.

At a value of 100 the warning curve is exceeded. The largest possible value is 200. (At this value the limits of our referenced standard are reached.) The higher the value the closer you are to the limits. Due to the safety reserve between the warning curve and the limits of the standard, even values of 200 do not mean danger yet.

Cardioman® measures in all relevant frequency ranges. It always displays the value of that frequency range where the field strengths get closest to the warning curve.

Normally the display shows very low values (e.g. 004) since you will be in safe areas most of the time. But the display reacts earlier than the display of the degree of exposure (LED line) described above. Thus, you can even recognize harmless field strengths e.g. to rate the characteristics of household appliances.

Acoustic signals

If the measured field strengths exceed the warning curve a beep occurs in addition to the visual signals. The velocity of the beep sequence increases with increasing field strength.

This acoustic warning allows you to have Cardioman® always with you without the necessity to continuously watch the displays.

Remark: If you switch on Cardioman® you will hear a beep.
But this is not connected to any danger.

Explanations

Where do dangerous field strengths occur?

In today's industrial world we are almost every time surrounded by sources of electric, magnetic or electromagnetic fields. The introduction of novel radio technologies (like cell phones, WLAN, etc.) the concentration further increases.

Several directives and standards include limits of field strengths for devices, machines, and facilities. Due to these regulations most devices, machines, and facilities are totally safe for pacemakers and ICDs.

However, some devices do not allow for a full shielding of the fields or even emit fields as an integrated part of their function (e.g. broadcasting stations). Moreover, devices can have a defect leading to higher emission than in normal operation.

Examples of sources that can influence the function of a pacemaker or ICD are strong magnets, motors, generators, current transformers, microwave ovens, induction heaters, high-voltage power lines, transmitters for radio, TV, telecommunication and radar, magnetic resonance scanners or anti-theft devices.

Cardioman® is used to find such exposures and protects you with more safety.

Where should you wear Cardioman®?

Since the influence of relevant sources of interference depends on their distance to the pacemaker or ICD you should bear Cardioman® very close to your pacemaker or ICD, e.g. in the breast pocket of your shirt or blouse. To probe special devices you can also use the warning device in your sprawled out hand.

Remark: Please take into account that magnetisable objects like a ball-pen in your breast pocket can distort the measurement. That is why we recommend not to store metallic objects close to Cardioman®.

Dependence on the distance

The range of electromagnetic fields differs for different sources. A good example are broadcast stations: Whereas long and medium wave stations can be received far away from the German borders, this is not possible with ultrashort wave (UKW) stations. These stations transmit different frequencies. And the range of electromagnetic fields depends on the frequency.

Broadcast stations have a very large coverage compared to household appliances or wireless phones. For many other devices the dangerous field strengths are even limited to just a few centimetres.

In the case of short-range fields it can happen that Cardioman® does not warn you as long as it has a certain distance from a device, but suddenly calls your attention when the distance is decreased. That is why you should preferably wear Cardioman® close to your pacemaker or ICD.

The antenna and the house symbols indicate whether the warning device measures a far-range (shining) or a short-range field (shining). In the case of far-range fields you can move over a large distance without a change of the warning signal. In the case of short-range fields, on the other hand, a small change of distance can lead to an immediate change of the degree of exposure and therefore of the intensity of the warning signal. There are also sources of interference with both kinds of fields. In this case both signals, antenna and house, are shining.

Maintenance

Your Cardioman® has been produced in accordance to highest standards. In order to maintain the proper function you should keep the following remarks in mind:

- Do not expose your Cardioman® to direct sunlight, heat, wetness, and dust. Do not drop the device and avoid shocks and strong vibrations.
- Clean Cardioman® only with a soft and dry cloth. Do not use wet cloths or aggressive cleaning agents like petrol or thinner.
- The LCD display is a sensitive component. Please do not put excessive pressure on it.
- Should your Cardioman® require maintenance, please contact the salesman you bought it from.

Safety remarks

(1) Cardioman® can not be used to detect danger due to electric shocks or malfunctions of pacemakers or ICDs due to vibrations.

(2) Cardioman® can only measure fields that are already there. If a device is switched on a sudden danger can occur that can not be recognized before the switch-on.

(3) The housing is sensitive to splash water. Please take care that Cardioman® does not get wet.

(4) The acceptable temperature range is between +5°C and +50°C. Please take into account that the measurements can be affected by lower temperatures. If Cardioman® was accidentally exposed to lower temperatures leaps of the displayed values can occur. However, the warning function is fully maintained under such conditions. After a few minutes the display should behave normal again.

(5) The display is sensitive to finger contact. Please do not touch the display during measurements.

(6) Please consider that Cardioman® is a sensitive electronic measurement device. Contact to your skin or contact to any devices can provoke field distortions that can lead to wrong values in turn. Turns or changes of fingering the device can lead to fluctuations of the measured values. Do not be surprised if different persons measure slightly different values in the same environment. You might know this effect from your radio. You can change the receiving

quality by touching the antenna. We have considered this effect when we defined the warning curve. You get a warning signal before your pacemaker or ICD is exposed to critical field strengths.

(7) Strong magnetic fields can lead to a mismeasurement if they are brought very close to the warning device. In these cases the measured values can change without noticeable reason. Please do not be bemused: Once Cardioman® has detected a magnet you should avoid this magnet even if the warning signal decreases or stops.

(8) Please do not use other wall power supplies to recharge the battery than the one included in delivery.

(9) You must not open Cardioman®. Any change of the device is not allowed.

(10) Cardioman® is equipped with a battery and other components affecting the environment. Please dispose it in accordance with legal regulations.

Technical data

Cardioman® is strictly oriented on the limits for the interference of pacemakers given in the German draft standard **DIN VDE 0848-3-1** „Safety in electric, magnetic, and electromagnetic fields, part 3-1: Protection of persons with active implantable medical devices in the frequency range of 0 Hz to 300 GHz“.

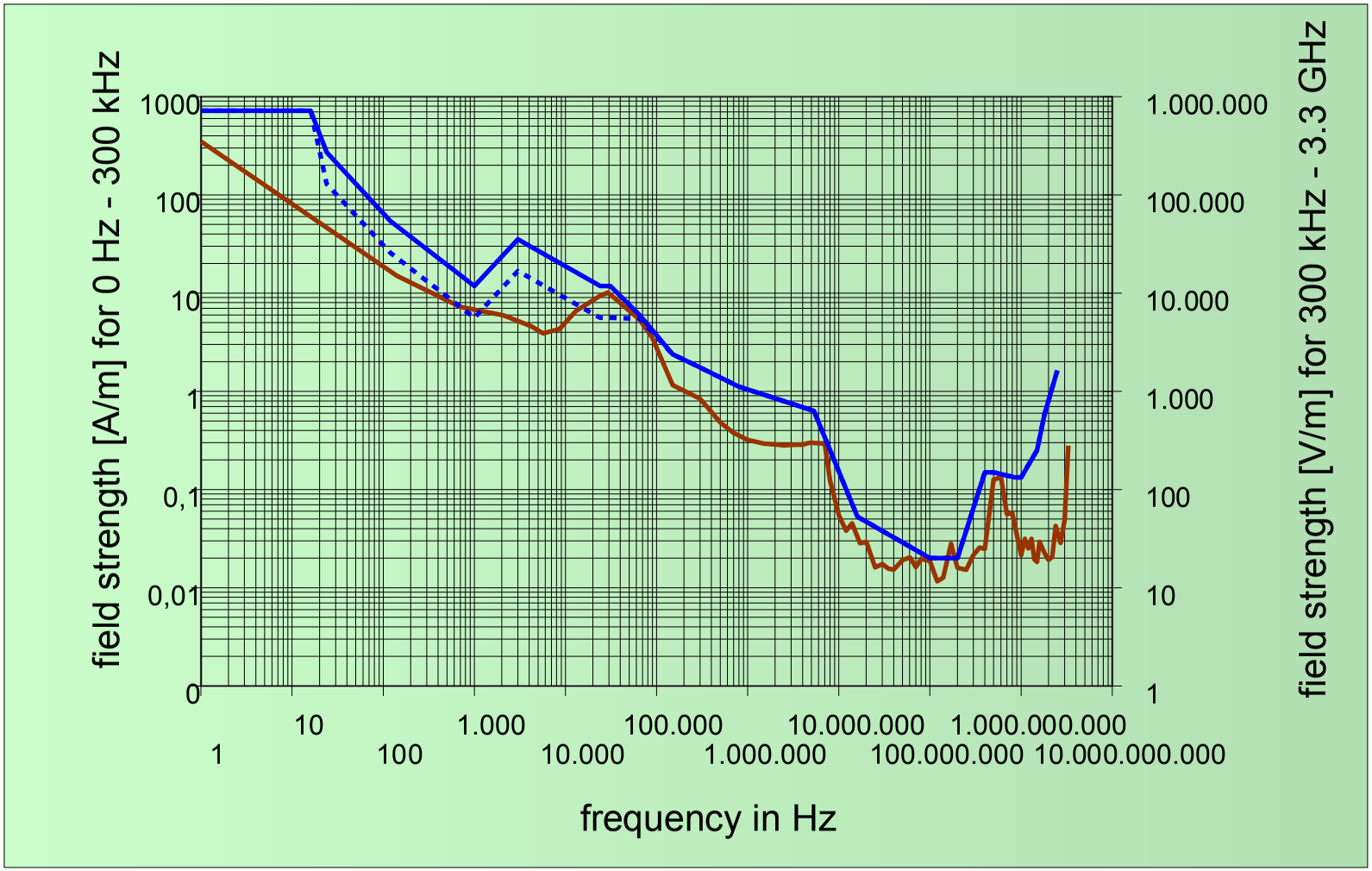
The limit curve of page 17 does include pacemakers of categories 0 and 1 as defined in the mentioned draft standard. It does not include the rare pacemakers of category 2. For that devices the limits can be below the warning curve at some points.

Frequency range:	0 Hz bis 3.3 GHz
Signals:	acoustic and visual warning
Dimensions:	h x w x d = 77 x 68 x 20 mm^3
Weight:	88 g
Li-ion battery:	1000 mAh / 3.7 V
Temperature range:	5°C – 50°C
Wall power supply:	5 V / 0.8 A (included in delivery)
Calibration interval:	We recommend a calibration after 3 years.

Response curve

The limits of the German draft standard DIN VDE 0848-3-1 have been defined in that way, that a malfunctioning of a pacemaker can be excluded with field strengths below the limits. Extensive measurements with a large number of pacemakers have been performed to prepare the standardization process. The limits strongly depend on the frequency of the interfering field.

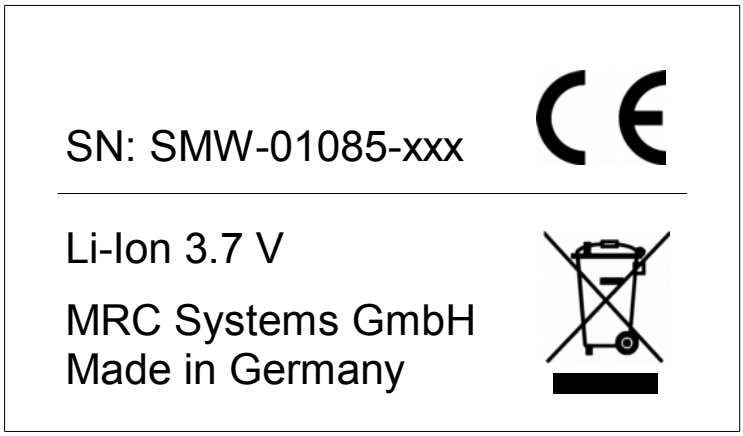
The warning curve of Cardioman® is defined with an additional safety reserve with regards to the draft standard's limits. The following diagram shows the course of the limits of the standard and the warning curve of Cardioman®. You can see: Even if the warning curve is exceeded there is no immediate danger. You can unexcited leave the source of interference.



Upper curve: Limit curve of DIN VDE 0848-3-1 for bipolar (solid) and unipolar (dashed) electrodes. Lower curve: Warning curve of Cardioman®

Marking

The following label is attached on the backside of Cardioman®:



The CE mark documents that Cardioman® fulfils the relevant European directives (EMC, low-voltage).

The crossed waste basket states, that MRC is connected to the German waste management system of electronic devices.
Please do not through away Cardioman® to the domestic waste.
Please bring it to an appropriate sorting station instead.

Vendor

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Subject to change without prior notice.

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